REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No. 04-171-KAJ

CONFIDENTIAL
FILED UNDER SEAL

TEVA'S OPENING BRIEF IN SUPPORT OF ITS CLAIM CONSTRUCTION

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Josy W. Ingersoll (# 1088)
Adam W. Poff (# 3990)
Karen E. Keller (# 4489)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899
Telephone: (302) 571-6600

MERCHANT & GOULD LLC
Mark D. Schuman
Ronald A. Daignault
Jeffer Ali
Jeffrey C. Brown
3200 IDS Center
80 South 8th Street
Minneapolis, MN 55402

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.

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I. INTRODUCTION

Teva has stipulated that its proposed ANDA product satisfies all the limitations of the claims of Glaxo's '249 patent except the following: "ethanol," "stabilizing effective amount," "2.5 % to 10% weight/volume ethanol," and "7% to 8% weight/volume ethanol." (Exhibit A at M002, June 30, 2005 Hearing Trans. p.5)[1]. Consequently, the Court need only interpret these four limitations.

Properly construed, ethanol simply means ethanol, "a chemical of the nomenclature CH_3CH_2OH, namely ethanol." The clause "stabilizing effective amount" means "an amount of a stabilizer that is sufficient to cause a statistically significant increase in the time it takes for an aqueous formulation containing ranitidine hydrochloride to lose 5 percent of the ranitidine present (the "t_{95}" value) as compared to the same formulation without the stabilizer."

The remaining limitations at issue should be construed to mean precisely how they read: "2.5% to 10% weight/volume ethanol" and "7% to 8% weight/volume ethanol" respectively.

II. THE LAW OF CLAIM INTERPRETATION

Claim interpretation is a matter of law to be decided by the district court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The objective of claim construction is to determine what a person of ordinary skill in the art, having read the written description and prosecution history, would understand the claims to mean. *Vanderland Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004); *Toro Co. v. White Consol. Indus., Ltd.*,

[1] As used in this brief, references to "Exhibit" are to the Exhibits attached to the Appendix supporting Teva's Brief in Support of its Claim Construction.

199 F.3d 1295, 1299 (Fed. Cir. 1999). "It is a 'bedrock principle' of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation omitted).

The Federal Circuit recently clarified the proper procedure to follow when construing the meaning of disputed claim terms. *See Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*, the Federal Circuit emphasized one rule above all others – the most important evidence in the construction of claim terms is that which is intrinsic to the patent. *See Phillips*, 415 F.3d at 1312; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Vitronics*, 90 F.3d at 1582.

In addition to the words of the claims themselves, the Court should always consult the written description (or specification) of the invention. *Markman*, 52 F.3d at 979. The written description is highly relevant to the claim construction process. *Phillips*, 415 F.3d at 1315. Specifically, the person of ordinary skill in the art – whose understanding of the claim terms is at the heart of the claim construction process – is presumed to have read the patent in its entirety, including the written description. *Id.* at 1313. Indeed, the specification has been deemed "the single best guide to the meaning of a disputed term," and serves as the "primary basis" for construing claim terms. *Id.* at 1315.

Likewise, the prosecution history frequently sheds light on the meaning of claim terms. *Id.* at 1317. It often demonstrates the inventor's understanding of the meaning of claim terms and the scope of the invention. *Id.* The prosecution history "can often

inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* For these reasons, courts should also consider the prosecution history, if in evidence, when construing claim terms.[2] *Markman*, 52 F.3d at 980.

Of course, a court always is free to consider extrinsic evidence to gain a better understanding of the background and technical aspects of the invention, so long as such inquiry is done within the context of the intrinsic record. *Phillips*, 415 F.3d at 1317-18. Extrinsic evidence "consists of all evidence external to the patent and prosecution history," including dictionaries. *Id.* at 1317. Indeed, dictionaries are given special consideration by the courts, as such texts (especially technical dictionaries) "endeavor to collect the accepted meanings of terms used in various fields of science and technology," and are generally viewed as unbiased and useful sources in claim construction. *Id.* (citing *Vitronics*, 90 F.3d at 1584, n.6).

III. ETHANOL

The term "ethanol" should be narrowly interpreted to mean "a chemical of the nomenclature CH_3CH_2OH, namely ethanol."

A. The Intrinsic Evidence

1. The '249 Patent Specification

The specification of the patent provides no explicit definition for ethanol, but it does repeatedly disclose and teach the use of ethanol, and only ethanol, to stabilize ranitidine oral solutions. Beginning with the title, the '249 patent informs the public that

[2] The prosecution history and the '249 patent are attached to the Joint Claim Construction, as required by the Court's Second Amended Scheduling Order, dated May 22, 2006. All cites to the intrinsic record in

it is directed to "AQUEOUS RANITIDINE COMPOSITIONS STABILIZED WITH ETHANOL." The abstract of the '249 patent further informs that ranitidine stability is "enhanced by the addition of ethanol." ('249 pat. at Abstract) (emphasis added). Similarly, after identifying several prior art formulations of ranitidine syrup, the '249 patent pronounces that ranitidine oral formulations "may be surprisingly enhanced by the addition of ethanol to the formulation." (Col. 1, lines 40-44) (emphasis added).

The '249 patent specification contains no data to indicate how ethanol stabilizes ranitidine, or how much stabilization is necessary. Instead, the '249 patent specification states that the amount of ethanol "is such that the resulting formulation has the enhanced stability." (Col. 1, lines 54-56). The specification then lists differing ranges of the amount of ethanol, starting at a range of "2.5 to 10% w/v,"[3] and decreasing within that range to an amount deemed "more especially" preferable, "7-8% w/v" of ethanol. (Col. 1, lines 56-60). No matter what the amount, ethanol is the sole constituent that is claimed to enhance the stability of ranitidine. The patent specification discloses only one formula as an "illustrative example of a formulation according to the invention," and that formula contains only ethanol. (Col. 2, lines 53-65).

The specification, however, makes no effort to define ethanol. There is certainly no mention in the '249 patent that ethanol should be defined as an organic compound "comprising a lower aliphatic hydrocarbon group having two carbon atoms and one -OH group," as Glaxo proposes in this litigation.

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this brief are to the Exhibits attached to the Joint Claim Statement.

[3] The short hand "w/v," as used in the '249 patent, is a reference to "weight/volume." ('249 pat., col. 1, ll. 54-60).

2. The Prosecution History

Similarly, the file history contains nothing to elucidate the definition of ethanol, although both the Examiner and Glaxo used the term frequently. Beginning with the first rejection of Glaxo's claims, the Examiner concluded that Glaxo's supposed invention was not patentable because "the art teaches the cojoining of ranitidine and an alcohol; e.g. ethanol," and stated that "the addition of a non-critical pH limit and non-critical amounts [of ethanol] are not seen as patentable limitations to the varioues [sic] claims." (G000265)[4] (emphasis added). The Examiner also rejected claims 1-10 as indefinite under 35 U.S.C. § 112, second paragraph, and claims 1-12 under 35 U.S.C. § 112, first paragraph. (G000264). Glaxo responded with an Amendment dated November 7, 1988. (G000267-270). The Examiner again rejected all of the claims on November 29, 1988. (G000271-272). Glaxo then abandoned its first application and filed a continuation application on April 28, 1989, which was given Serial No. 07/344,620.

On June 28, 1989, the Examiner once again rejected all of the claims. (G000130-135). Glaxo responded on October 30, 1989, by amending its claims to state that the claimed invention is to include a "stabilizing effective amount of" ethanol. (G000139) (emphasis added). Glaxo included this claim amendment to "functionally" define "the amount of ethanol present." (G000140) (emphasis added). Glaxo also argued that the prior art cited by the Examiner in the first rejection did not teach one of skill in the art "to expect that the stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of ethanol and does not suggest a presence of ethanol in such compositions." (G000141-142) (emphasis added). Glaxo continued by arguing that the only fair

[4] File history documents, referenced herein as "G000111 through G000308" are attached as Exhibits 2 and 3 to the Joint Claim Construction Statement filed contemporaneously with this brief.

inference from the prior art references "is that ranitidine hydrochloride must be reasonably stable in ethanol since ethanol is used as a solvent for recrystallization." (G000142) (emphasis added).

On November 14, 1989, the Examiner again rejected the amended claims, noting that the "art clearly precludes applicants claims to ranitidine and ETOH."[5] (G000161) (emphasis added). The Examiner also noted, "[a]s for the allegation of enhanced stability, it has not been demonstrated for the compositions urged as contrasted with any of other pH parameters." *Id.* The Examiner made the November 14, 1989, rejection final. (G000162). Glaxo responded by abandoning that application and filing a separate continuation application. (G000164-166). On May 4, 1990, the Examiner again rejected all claims of the application for the identical reasons set forth in the June 28, 1989, Office Action. (G000169-171).

Glaxo responded with another amendment on October 31, 1990. Glaxo argued that one of ordinary skill would not be lead by the prior art to "in any way expect the stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of ethanol and does not suggest the presence of ethanol in such compositions." (G000175) (emphasis added).

The Examiner again rejected Glaxo's claims, citing new prior art that had been disclosed by Glaxo. (G000198-201). The Examiner also challenged Glaxo to demonstrate, through experimental data, that its purported invention – the use of ethanol in the formulation – produced "any unexpected results," showing "a definite improvement over" Glaxo's prior patent. (G000200). The Examiner noted that because

[5] "ETOH" is chemical shorthand for "ethanol." *The Hawley's Condensed Chemical Dictionary*, 11th Edition (1987), p. 477 (Exhibit B at M005).

a prior Glaxo patent taught "an aqueous composition of ranitidine, it is considered well within the state of the art to choose ethanol as an additive which would be considered pharmaceutically acceptable when formulating this composition." *Id.* (emphasis added).

On May 10, 1991, Glaxo requested reconsideration of the Examiner's rejection, this time arguing that "there is a clear disincentive against the use of ethanol in aqueous formulations" because ranitidine is used to treat peptic ulcers and related conditions that can be aggravated by "alcohol (i.e., ethanol)." (G000206) (emphasis added). Glaxo argued that "only by the present invention," would one of ordinary skill in the art recognize the stabilizing benefits of ethanol in the formulation. *Id.* (emphasis added).

In further support of Glaxo's claim to the unique and specific benefits of ethanol to stabilize ranitidine, Glaxo submitted the Declaration of one of its scientists, Dr. John Hempenstall. (G000208-211). Dr. Hempenstall's declaration purported to provide the experimental data the patent Examiner had sought since the November 14, 1989 rejection. Dr. Hempenstall, who at the time was "a Research Leader" in the Pharmacy Division of Glaxo, declared that ethanol, in Glaxo's ranitidine formulation, resulted in a "surprising enhancement in the stability of the ranitidine...." (G000209). The Examiner then allowed all of the pending claims. (G000212-214).

In summary, both the Examiner and the applicant discussed ethanol in terms of the prior art throughout the prosecution of the patent. Not once did Glaxo contend that the term "ethanol" should be given any special meaning. Indeed, throughout the prosecution, both Glaxo and the Examiner assumed that ethanol meant ethanol. Even when Glaxo deviated from describing ethanol, it used the term "alcohol," the common synonym of ethanol. It did not use the phrase "an organic compound comprising a lower

aliphatic hydrocarbon group having two carbons and one -OH group" even once throughout the entirety of the prosecution of the patent. The only question, then, is what one of ordinary skill understands ethanol to mean.

B. The Extrinsic Evidence

Webster's New Collegiate Dictionary defines ethanol by directing the reader to the definition of "alcohol." Alcohol is defined as "a colorless volatile flammable liquid C_2H_6O that is the intoxicating agent in fermented and distilled liquors and is used also as a solvent – called also ethyl alcohol." (Exhibit C at M09-M010). The Hawley's Condensed Chemical Dictionary, 11th edition, (the same edition relied upon by Glaxo's expert, Dr. Anderson) defines "ethanol" by directing the reader to the definition of "ethyl alcohol," which is defined as "alcohol; grain alcohol, ethanol; EtOH," and "C_2H_5OH."[6] (Exhibit B at M 005). Even the "Handbook of Chemistry and Physics" text, another treatise selected by Glaxo's expert, defines "ethanol" simply as "alcohol. Ethyl alcohol. Methyl carbinol. C_2H_5OH." (Exhibit D at M014). Each of these references has in common the simple use of a chemical formula to identify and define ethanol.

Reduced to its essence, ethanol has its most unambiguous definition in its chemical formula, CH_3CH_2OH. The public (including Teva) is justified in relying on Glaxo's unequivocal, unambiguous, and repeated statements to the Patent Office that the use of "ethanol" was Glaxo's invention.

Glaxo does not appear to dispute the fact that the intrinsic evidence does not define ethanol in any unique or special manner. Yet, Glaxo's definition adds "an organic

[6] Note that three of these terms, "ethanol," "alcohol," and "EtOH" were all used by either the Examiner or Glaxo interchangeably throughout the prosecution of the '249 patent. (G000265) (Examiner uses "alcohol; e.g. ethanol"); (G000161) (Examiner uses "Etoh" to refer to ethanol); (G000206) (Glaxo uses "alcohol (i.e. ethanol")).

compound comprising a lower aliphatic hydrocarbon group having two carbon atoms and one -OH group," among other extraneous language, to the chemical formula of ethanol. Glaxo seeks to characterize ethanol in such a manner so that it can bootstrap its infringement argument into the definition of "ethanol." Teva does not use ethanol in its formulation, so there can be no literal infringement no matter how ethanol is interpreted. Teva uses Redacted , according to Glaxo's expert, is (Exhibit E at M021, Anderson 3/16/06 Expert Report, ¶ 74).

Glaxo hopes to use its definition as a springboard for its argument that Teva infringes under the doctrine of equivalents. Indeed, Glaxo's motivation for its construction is transparently betrayed by its own expert, Dr. Anderson, who mimics most of Glaxo's proposed definition of ethanol word for word when describing Redacted , a wholly different chemical compound. (Exhibit E at M017- M018, Anderson 3/16/06 Report at ¶ 34) (noting his opinion that the '249 covers the use of ethanol Redacted

Glaxo's proposed construction violates the rules of claim construction. It is settled law that claims must not be construed with reference to an accused product. *See SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) ("It is only after the claims have been construed without reference to the accused device that the claims, as so construed, are applied to the accused device to determine infringement."). Glaxo's construction is a semantics exercise, seeking to make the term "ethanol" look as much as possible like Redacted as used by Teva in the accused formulation.

By using words like "comprising" and "a" in its proposed claim construction, Glaxo also hopes to expand the definition of ethanol to any lower, aliphatic organic compound with at least two carbon atoms and one –OH group. *See Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1344-45 (Fed. Cir. 2003) ("Comprising is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *KCJ Corp. v. Kineic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) (An indefinite article 'a' in patent parlance carries the meaning of one or more in open-ended claims containing the transitional phrase comprising.). However, adopting Glaxo's proposed construction brings just about every other alcohol and non-alcohol compound with at least two carbon atoms and one -OH group within the scope of the claims. There is no intrinsic or extrinsic support for such a broad construction of such an unambiguous word like "ethanol." Consequently, Glaxo's proposed construction should be rejected.

Further, district courts are consistently cautioned by the Federal Circuit to be careful not to import undue limitations into the definitions of claim terms when they are not necessary. *See Rensha PLC v. Marposs Societa per Axioni*, 158 F.3d 1243, 1248 (Fed Cir. 1998) ("If we need not rely on a limitation to interpret what the patentee meant by a particular term or phrase in a claim, that limitation is 'extraneous' and cannot constrain the claim.") (citations omitted); *see also Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 950 (Fed. Cir. 1993) ("It is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.") (quoting *Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988)). The

extraneous language proposed by Glaxo is not necessary to define the common understanding of the term "ethanol." Indeed, no less than three dictionaries use ethanol's chemical formula as a common definition for ethanol. Glaxo's proposed construction should therefore be rejected.

The Federal Circuit directs courts to give claim terms their ordinary meaning absent an express intent by the inventor to impart a different meaning to the terms at issue. *Phillips*, 415 F.3d at 1312-13 (citing, among other cases, *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Further, if the word is a technical term, it "is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996). Here, there is no indication in the intrinsic evidence that the term ethanol was meant to refer to anything but the chemical compound commonly understood as ethanol. Therefore, the Court should not look beyond the plain and ordinary meaning of the word "ethanol" to construe it as "a chemical nomenclature of CH_3CH_2OH, namely ethanol." No further description is necessary to fully and completely define the term "ethanol" to those skilled in the art.

IV. STABILIZING EFFECTIVE AMOUNT

The term "stabilizing effective amount" is properly construed to mean "an amount of a stabilizer that is sufficient to cause a statistically significant increase in the time it takes for an aqueous formulation containing ranitidine hydrochloride to lose 5 percent of the ranitidine present (the "t_{95}" value) as compared to the same formulation without the

stabilizer." Glaxo provides this definition in the prosecution history of the '249 patent through the experimental evidence it supplied to the Examiner and upon which the Examiner relied. The declaration gave a methodology for determining whether the added stabilizer substantially enhanced the stability of ranitidine solution. Glaxo is bound by this methodology – the only indication in the patent or file history of what "a stabilizing effective amount" means.

A. The Intrinsic Evidence

The '249 patent does not explicitly define what "a stabilizing effective amount" means. It does, however, state that the invention is directed to substantial stability enhancement:

> We have now surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of ethanol to the formulation.

(Col. 1, lines 40-44) (emphasis added). The '249 patent does not, however, offer a specific definition of the clause "a stabilizing effective amount."

Throughout most of the file history, the applicants and Examiner also did not define what "a stabilizing effective amount" meant. The Examiner did, however, initially reject Glaxo's claims as indefinite, to which Glaxo responded with its first amendment adding "stabilizing effective amount" to claim 1. (G000139). Glaxo described its amendment as an effort to "functionally define[]" the amount of ethanol present in the formulation. (G000140). The Examiner accepted the amendment at face value, but nonetheless rejected the claims as unpatentable. (G000198-201). The Examiner noted that because Glaxo's prior ranitidine patent "teaches an aqueous composition of ranitidine, it is considered well within the state of the art to choose ethanol as an additive

which would be considered pharmaceutically acceptable when formulating this composition." (G000200). The Examiner then asked for evidence from Glaxo showing that the addition of ethanol was more than just "a choice among known conventional excipients." *Id.*

Glaxo ultimately responded to the Examiner's request for data by submitting a declaration from one of its scientists, Dr Hempenstall. (G000208-211). In that declaration, Mr. Hempenstall, a Glaxo scientist with a doctorate in Pharmaceutical Sciences from the University of Aston in Birmingham, summarized to the Patent Office an analysis of data performed by others at Glaxo and argued the data showed substantial enhancement. (G000209). Dr. Hempenstall declared "[t]he advantageous effect resulting from the addition of ethanol to an aqueous based ranitidine formulation can readily be determined by comparing the stability of the ranitidine in a formulation according to the present invention and the same formulation but without the ethanol added." *Id.* at ¶ 5 (emphasis added).

To make this comparison, Dr. Hempenstall first recognized that "acceptable shelf life for an aqueous formulation containing ranitidine hydrochloride is considered to be the time at which no more than 5% of the ranitidine present in the formulation has degraded."[7] (G000210 at ¶ 6) (emphasis added). Dr. Hempenstall's t95 results were "calculated at the lower 95% confidence limit." (G000210). A "confidence limit" is well known as a statistical analysis of data. *See Reference Manual of Scientific Evidence* 376 (1994) (a confidence interval is derived using a particular model of statistical error). Dr. Hempenstall, in his declaration, then compared the t_{95} values for solutions containing ethanol to solutions not containing ethanol. (G000209 at ¶ 5). Dr. Hempenstall observed

that an increase in shelf life of six months occurred at 30°C, an increase he deemed "a highly significant and valuable improvement." (G000211 at ¶ 6, p. 4) (emphasis added). Dr. Hempenstall, in a prior litigation, testified that Glaxo performed a statistical analysis on the data to determine its significance before submitting his declaration to the Patent Office. *Glaxo v. Pharmadyne*, 32 F. Supp. 2d. 265, 311 (D. Md. 1998) (noting that "Before Dr. Hempenstall prepared his declaration he asked for statistical analyses of the comparative studies that Glaxo had conducted on ethanol and non-ethanol solutions" partly because his predecessor questioned "whether the ethanol stability effect was significant.") (emphasis added).

In sum, Dr. Hempenstall's declaration establishes the following methodology for the term "stabilizing effective amount:"

1. The t_{95} value for a solution containing the stabilizer must be measured;

2. The t_{95} value for a solution devoid of the stabilizer must be measured; and

3. The t_{95} value for the stabilized solution must be compared with the t_{95} value for the unstabilized solution and the increase in t_{95} time due to the stabilizer must be statistically significant.

Dr. Hempenstall ultimately concluded that his data showed that "a significant and surprising enhancement in the stability of the ranitidine is achieved by the addition of ethanol." (G000209 at ¶ 5) (emphasis added). Thus, the intrinsic record teaches that to know whether any amount of excipient added to a ranitidine solution produces a substantial enhancement of the solution, a statistical comparison between the t_{95} values for the same solution both with and without the stabilizing component must be made.

[7] This is also known as the t_{95} value. (Exhibit A at M019-M020, Anderson 3/16/06 Report at ¶ 44.)

B. The Extrinsic Evidence

Glaxo agrees that the time at which 5% ranitidine degradation occurs is commonly understood as Redacted (Exhibit E at M019-M020, Anderson Report at ¶44 (stating Redacted). Further, Glaxo's expert correctly observes that the t_{95} value Redacted *Id.* Importantly, Glaxo's expert also agrees that the term "substantially enhanced" as used in the '249 patent, Redacted .." (Exhibit F at M024, Anderson, April 24, 2006 Rebuttal Report, ¶ 27.) In fact, Glaxo's expert unequivocally agrees that Dr. Hempenstall's declaration, submitted to the Patent Office during prosecution, demonstrated to the Patent Office a statistically significant enhancement of the stability of ranitidine:

Redacted

Id.

The proper construction, therefore, of "a stabilizing effective amount" is one that identifies what a substantial increase in shelf life means, and further acknowledges how to determine that increase. Just as Dr. Hempenstall demonstrated to the Patent Office, "a stabilizing effective amount" is properly construed to mean "an amount of a stabilizer that is sufficient to cause a statistically significant increase in the time it takes for an aqueous formulation containing ranitidine hydrochloride to lose 5 percent of the

ranitidine present (the "t_{95}" value) as compared to the same formulation without the stabilizer."

Glaxo's definition ignores the fact that to get its patent, it had to submit the tests and results run by Dr. Hempenstall. Only then did the Examiner allow the claims. Dr. Hempenstall's methodology must therefore define the functional term "stabilizing effective amount." Glaxo's definition is merely a circular exercise in redundancy, providing no link to the critical data that Glaxo submitted to the Patent Office.

V. 2.5% TO 10% WEIGHT/VOLUME ETHANOL AND 7% TO 8% WEIGHT/VOLUME ETHANOL

The proper construction of "2.5% to 10% weight/volume ethanol" and "7% to 8% weight/volume ethanol," appearing in claims 2, 3, 11, and 12 respectively, are simply "2.5% to 10% weight/volume ethanol" and "7% to 8% weight/volume ethanol." This Court should not construe these terms beyond their normal and customary meaning. Both limitations are clear and unmistakable in that they define various numerical ranges of the amount of ethanol to be used in the claimed formulations, calculated as a percentage of the weight compared to the volume of the total formulation. None of these claims include the limitation that the stated ranges for the amount of ethanol have a "stabilizing effect" on the ranitidine solution—which is what Glaxo urges--except to the extent that such a limitation is imposed upon claims 2 and 3 by virtue of the separate limitation in the independent claim 1 from which they depend. There is no need to import any further limitations into any of these terms. Indeed, when Glaxo amended claim 1 to include "a stabilizing effective amount" of ethanol, it could have also amended the claims 2, 3, 11 and 12 in the same manner, but it did not. The law presumes that Glaxo meant to maintain a difference between claim 1 and the other claims with numerical ranges when it

had the opportunity to add the "stabilizing effective amount" language to the numerical range claims, but did not. *See Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295 (Fed. Cir. 1999) ("There is presumed to be a difference in meaning and scope when different words and phrases are used in separate claims.") (citing *Tandon Corp. v. ITC*, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

A. The Intrinsic Evidence

Claims 2 and 3 both recite the pharmaceutical composition of claim 1 with an added limitation that identifies specific ranges for the amount of ethanol to use in the formulation. (Col. 3, lines 5-7; 8-10). Claim 2 identifies "2.5% to 10% weight/volume ethanol." Claim 3 states a narrower range, "7% to 8% weight/volume ethanol." *Id.* Both claims identify the amount of ethanol as an amount "based on the complete formulation." *Id.* Claim 11 is an independent claim that also more specifically defines the amount of ethanol, "7% to 8% weight/volume ethanol." *Id.* at 4: 10-16.

The '249 specification provides ample confirmation that both range limitations mean precisely what they say:

> The amount of ethanol in the formulation for oral administration, expressed as a percentage of the complete formulation on a weight/volume basis, is preferably within the range 2.5 to 10%, and more particularly between 5 to 10%, more especially 7-8%.

(Col. 2, lines 30-34). The specification identifies each claimed range as the "preferred" and "more particularly preferred" ranges for the amount of ethanol to use in the claimed formulations, and concludes with an example of a complete recipe of one formulation, using 7.5% weight/volume based on the complete formulation. (Col. 2, lines 53-64). No further construction is necessary to fully understand that the numerical ranges claimed in claims 2, 3, 11 and 12. They mean simply what they say.

The prosecution history reveals no effort by Glaxo to impart any unique definition to the ranges for the amount of ethanol included in claims 2, 3, 11 or 12. In fact, the claims that recited specific ranges for the amount of ethanol to use in the formulations survived through prosecution without amendment. (Compare col. 3, lines 5-8 to G000120) (reciting identical language for claim 2). More particularly, while Glaxo amended the originally filed claim 1 in order to "functionally define" that claim, it did not so amend claims 2, 3, 11, or 12. Glaxo had the opportunity to amend its claim language in these claims during prosecution, but it did not. It is not for this Court to add limitations that Glaxo, itself, apparently chose not to add during prosecution.

As issued, claims 2, 3, 11 and 12 recite a formulation of ranitidine with specific ranges for the amount of ethanol. None of the issued claims address whether the amount of ethanol so specified is "a stabilizing effective amount," or not. The law does not allow extraneous limitations to be read into claim limitations. *DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433-34 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 986 (1988). Glaxo's proposed construction reads a limitation into the ranges found in claims 2, 3, 11 and 12 that is not necessary, and was not inserted by Glaxo during prosecution. Glaxo's definition should be rejected.

VI. NO FURTHER ELEMENTS SHOULD BE CONSTRUED

Glaxo proposes a construction of "aqueous formulation for oral administration," found in claims 1 - 10, and "aqueous formulation of ranitidine suitable for oral administration," found in claims 11 and 12. Both of these phrases need not be construed, however, because Teva has stipulated that its proposed ranitidine formulation meets these

phrases.[8] The Federal Circuit has been clear that a district court need not (and should not) repeat or restate every claim term when construing patent claims. *U.S. Surgical Co. v. Ethicon*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). To the contrary, "[c]laim construction is a matter of resolution of disputed meanings and technical scope," focused on clarifying, only when necessary, what the patentee's claims are. *Id.* (emphasis added). The claim construction of the phrases proposed by Glaxo pertaining to "aqueous" formulations are not at issue in this case, and should not be construed.

[8] The phrases are in the "preamble" to each of the claims. Under Federal Circuit precedent, a claim's preamble generally does not serve as a limitation of a patent claim. Rather, a preamble merely establishes the background or context for the patent claim. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) ("Generally, the preamble does not limit the claims."); *accord DeGeorge v. Bernier*, 768 F.2d 1318, 1322 n.3 (Fed. Cir. 1985).

VII. CONCLUSION

For the reasons stated above, Teva respectfully urges the Court to adopt its proposed constructions of the disputed claim terms presented for construction.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (# 1088)
Adam W. Poff (# 3990)
Karen E. Keller (# 4489)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899
Telephone: (302) 571-6600

MERCHANT & GOULD LLC
Mark D. Schuman
Ronald A. Daignault
Jeffer Ali
Jeffrey C. Brown
3200 IDS Center
80 South 8th Street
Minneapolis, MN 55402
Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.

Dated: June 30, 2006

CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on June 30, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

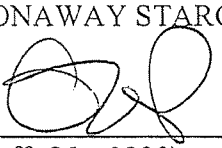
Francis DiGiovanni Esquire
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

I further certify that on June 30, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY FEDERAL EXPRESS

Brian P. Murphy, Esquire
Thomas Puppa, Esquire
Morgan Lewis & Bockius, LLP
101 Park Avenue
New York, NY 10178-0060

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Adam W. Poff (No. 3990)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
apoff@ycst.com
Attorneys for Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Indusstries, Ltd.

CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on July 10, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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Morgan Lewis & Bockius, LLP
101 Park Avenue
New York, NY 10178-0060

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Adam W. Poff (No. 3990)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
apoff@ycst.com
Attorneys for Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.